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Drinking Water Regulations

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1.1 EU DIRECTIVE ON DRINKING WATER – PAST, PRESENT AND FUTURE

1.1.1 EU Water Legislation

Water is one of the most comprehensively regulated areas of EU environmental legislation. Early European water policy began in the 1970s with the adoption of political programmes as well as legally binding legislation. As regards programmes, the First Environmental Action Programme covered the period 1973–76. Parallel with political programmes, a first wave of legislation was adopted, starting with the 1975 Surface Water Directive and culminating in the 1980 Drinking Water Directive 80/778/EEC. This initial directive was based upon the scientific and technical state of the art of 25 years ago. Since then both scientific and technological knowledge and the approach to EU legislation has changed. It was therefore necessary not only to adapt the original directive to bring it in line with the current scientific and technical progress, but also to bring it into accordance with the principle of subsidiarity by reducing the number of parameters that member states were obliged to monitor and by focusing on compliance with essential quality and health parameters.

1.1.2 The Drinking Water Directives – Revision Processes

In 1993 the commission organized a European drinking water conference in Brussels to consult all stakeholders in the supply of drinking water about the revision of the

DWD then in force. This resulted, in 1998, in the adoption and entry into force of the current DWD 98/83/EC (OJ L 330, 5.12.98). The 1998 DWD had to be transposed into national legislation 2 years after coming into force, which was at the end of the year 2000, and had to be complied with by the end of 2003 (with some exceptions for critical parameters such as lead and disinfection by products).

In the meantime the commission started preparations for the revision of the new DWD some 5 years after it came into force. This revision process is foreseen in the DWD. Exactly 10 years after the consultation of European stakeholders, the commission started to consult stakeholders on the need for revision of DWD 98/83/EC. This time 25 countries will be involved

1.1.3 Main Aspects of the Drinking Water Directives

Related Community legislation

The first generation of EU water legislation consisted of more or less isolated pieces of legislation, with little or no cross-referencing. The previous DWD 80/778/EEC only makes reference to one piece of EU legislation, namely the Council Directive on the Quality of Surface Water, intended for the abstraction of Drinking Water (75/440/EEC). The current DWD refers to a number of other directives that are related to the original directive or have interactions with that directive:

- the Plant Protection Directive (91/414/EEC) and the Biocides Directive (98/8/EC) both relevant for the pesticides parameter in the Directive and

- the Construction Products Directive (89/106/EEC), relevant for materials and appendages used in the production and distribution of drinking water.

In future revisions of the DWD, attention will be paid to an integrated approach to EU water legislation as the directive has to be brought into line with important developments such as the Water Framework Directive and the European Acceptance Scheme (under development) for materials in contact with drinking water.

Integration of EU water legislation does not only imply compliance with the requirements of various related directives but will also involve harmonization and streamlining of reporting requirements. Reporting requirements will have to address compliance and the state of, and trends in, the quality of aquatic environments.

Principles for drinking water directives

The underling principle for the previous DWD was not specified other than that it had the objective of ‘setting standards for human health protection’. The current

DWD aims to protect human health from the adverse effects of contamination of water intended for human consumption by ensuring that it is 'wholesome and clean'. This applies to all water intended for human consumption, as well as to water used in the production and marketing of food, with certain exceptions. Member states are required to monitor the quality of drinking water and to take measures to ensure that it complies with the minimum quality standards. It also lays down a number of requirements for reporting to the commission, and for making information available to the public regarding the quality of drinking water. The directive is based on a number of principles that have been laid down in the Treaty, such as the subsidiarity principle and the precautionary principle. Unlike the early Community legislation, the new Treaty of the European Union states that no Community legislation should go beyond what is necessary to achieve the objectives of the treaty. For drinking water legislation this implies that the high number of parameters in the previous directive has been reduced the better to focus on what are essential and health related parameters in the whole European Union, leaving member states free to add other parameters if they see fit. A HACCP-based directive might reduce the number of parameters even further.

Other principles of the current directive are the precautionary principle, sustainable use of water and water source protection, and of course the political compromise that goes hand in hand with the process of adoption of new legislation by the member states. If future legislation should be based on risk assessment and risk approach, the added value of such an approach should be made clear. Also such an approach should offer at least the same protection level as the current legislation in force. Other basic principles of the directive are the stand-still principle, implying that the implementation of the directive should not result in deterioration of the current level of protection offered in the member states. Also water source protection and sustainable use of water are important aspects of the directive. Also, as in all legislation, compromises are made to accommodate political aspects in the various member states. Future legislation will evidently have to be based on the principles as worded in the treaty, but after careful weighing of advantages and disadvantages of a risk analysis based approach, the principles of such an approach could easily be incorporated into the directive.

Types of water covered by the DWD

The previous DWD covered all water intended for human consumption except for natural mineral waters, medicinal waters, and water used in the food industry not affecting the final product. The current directive covers the same types of waters and has the same exceptions. It also makes it possible for member states to exempt other types of water from the directive, such as hot tap water, second grade water for non-ingestive uses and supplies of less than 10 m^3/day. As yet it is not known if there is a need to change the coverage of the DWD in future revisions of the directive.

Parameters and parametric values

The previous DWD listed more than 62 parameters often together with parametric values such as MACs (maximum allowable concentration), guideline values and minimum levels. Parameters included organoleptic, physico-chemical parameters, undesirable substances, toxic substances, microbiological parameters and minimum requirements for water that had been subject to water conditioning processes to remove hardness. Not all parameters actually had a parametric value in the directive and also no mention was made of the scientific justification for the parameters and the values in the directive. Substances that were used in the preparation of drinking water should remain in the water at values below the parametric value for these substances. One of the main reasons for the revision of the old directive was to restrict the number of parameters to include only essential and health related parameters that are of importance in the many countries of the European Union. It is then left to member states on the basis of the subsidiarity principle to add parameters or to set stricter values as and where necessary but with no breaching the treaty with respect to the rules of fair trade within the EU. The number of parameters is restricted to a total of 48 (microbiological, chemical and indicator) parameters. All parameters that are included in the directive have a parametric value or mention of the fact that water 'should be acceptable to consumers and no abnormal change' should occur. All parametric values are mandatory and guide level values no longer exist in the directive. For future revisions of the DWD discussions could result in new and additional parameters or in even fewer parameters. New parameters might, for example, be endocrine disrupting chemicals, pharmaceuticals, protozoa such as *Giardia* spp. and *Cryptosporidium* spp. or *Legionella* spp. In a risk-analysis based approach it might also be possible that one parameter may have more than one parametric value in various parts of the whole water production and supply process.

Parameters in DWD 98/83/EC

In this DWD a balance is struck between microbiological and chemical risks. Disinfection of drinking water carries the risk of contamination by formation of products that are harmful to human beings, such as trihalomethanes and bromate. However, disinfection reduces the risk of exposure to pathogenic bacteria in the water. Water quality is more than the 48 parameters listed in the current directive. Some parameters that might cause a threat to human health are not yet known. Therefore the DWD has to reinforce the precautionary principle, an important article (Article 4(1)a), which states that water intended for human consumption should be 'wholesome and clean'. Article 10 of the DWD ensures that chemicals used in the preparation of drinking water should not remain in the final product in concentrations higher than absolutely necessary. Another important aspect of Article 10 is the reference to the Construction Products Directive on materials in contact with drinking water during

its distribution, in order to avoid an adverse effect on the quality of drinking water by pipe materials, for example.

Basis of parametric values

In setting the parametric values for the various parameters, both short term/acute effects and long term chronic effects have been taken into account as and where appropriate. Basic principles are that the quality of the water should be such that consumers can drink and use water for domestic purposes for a lifetime without the risk of adverse health effects. Also special attention is paid to the protection of vulnerable groups such as children and pregnant women, for instance in setting the values for lead, nitrate and nitrite (babies). WHO guideline values for drinking water, adopted in 1992, were used as a basis for setting parametric values in the DWD, wherever there was a health-based guideline value available. For some parameters a different approach was used, and for others advice was asked of the CSTEE (Scientific Advisory Committee). Parameters in the last category were lead, PAH, pesticides, tri- and tetra-, copper and boron.

Microbiological parameters

The parametric values for the relevant specified microbiological parameters are zero as any positive result indicates the likely presence of pathogenic microorganisms and calls for an immediate response.

Carcinogenic parameters

For genotoxic carcinogens there is normally no threshold below which there is no risk to human health. The WHO applies a criterion for individual carcinogens that implies that there should be no more than one excess cancer in a population of 10^5 resulting from a lifetime's exposure. In the DWD a stricter criterion was used, which implies that there should be no more than one excess cancer in a population of 10^6 resulting from a lifetime's exposure.

Other considerations

A very practical consideration in setting parametric values is the availability of fit-for-purpose analysis methods at the required detection level. For three parameters in the DWD it was, at the time of adoption, not possible to detect the substances at a level that would sufficiently protect human health. For these three parameters, epichlorohydrin, acrylamide and vinyl chloride, a parametric value was adopted

that was below the then achievable limit of detection, and for these parameters it was decided to regulate levels in drinking water through product specifications. A second principle for setting parametric values is the availability of treatment methods to ensure that the required removal of the substances could be achieved with the available treatment techniques. Finally, a balance was struck between the risk to human health from the consumption of water not meeting the high standards foreseen in the DWD and the risk from interruption of the water supply (sometimes applying parametric values not as strict as that corresponding to the one in a million criterion).

Sampling and monitoring

The previous DWD 80/778/EEC defines minimum monitoring requirements with a sampling and analysis frequency that is related to the amount of water supplied. A distinction is made between current monitoring, periodic monitoring and occasional monitoring. The current DWD 98/83/EC uses a similar approach where minimum monitoring effort is defined in relation to the amount of water supplied. A regular check of the water quality is defined for some key parameters in so-called check monitoring, and a more comprehensive check of the water quality including all other parameters is carried out with a much lower frequency in so-called audit monitoring. The main difference between both directives is the fact that under the current DWD sampling and monitoring is carried out at the consumer's tap unless it relates to parameters that do not change between the production plant and the tap. Sampling and monitoring under the DWD is, in principle, a check at the last minute and is, in principle, always too late. In the case of water not complying, it has already been supplied to the customer and been consumed. A risk-assessment and risk-management based approach could well cause a major change in sampling and monitoring strategies for drinking water. Moving the place of check and control further back in the production chain from raw water source to tap may be beneficial for some parameters.

Quality control and assurance

Quality control in the 80/778/EEC DWD was restricted to the mention of analytical reference methods. The current DWD goes much further by making ISO/CEN methods compulsory and defining performance criteria for (mostly) chemico-physical parameters. Furthermore, member states need to have some QC/QA system in place in the approved laboratories for drinking water analyses. At the time of adoption of the DWD it was not judged possible to apply an accreditation system for all member states, but it is expected that this will be an additional requirement in the near future.

As future regulation might well be based on risk analysis and approach, the QC/QA system is of vital importance not only to control process performance but also to validate and guarantee the quality of drinking water at the tap.

1.1.4 Revision of the DWD and WHO Guidelines

WHO has adopted the HACCP based approach for drinking water in the so called 'water safety plans'. The European Commission is currently considering whether it would be appropriate to follow this concept in the revision of the DWD.

Issues that will be addressed by the experts in the revision will include such basic questions as how can the underlying principles of the treaty (and the DWD) be maintained and safeguarded in a risk assessment approach:

- subsidiarity principle;
- stand-still principle;
- precautionary principle.

The main question is, of course, how can the same or even higher level of protection of European citizens continue to be guaranteed.

1.1.5 Conclusions

The EU regulation on drinking water has contributed significantly to the supply of safe and wholesome drinking water to European citizens. The current DWD 98/83/EC even improves on that by setting requirements for the quality of drinking water at the consumer's tap. Council directives on drinking water are to a large extent based on WHO guidelines and it is therefore logical that any developments in these guidelines will have to be considered in the revision of the DWD. It is expected that the underlying principles of the current DWD will be further strengthened by a HACCP-like approach. When applied properly and consistently, the added value of a risk-assessment based approach, together with the existing framework of the directive, will be a powerful tool for addressing new and, as yet, partly unknown threats to drinking water such as, for instance, pharmaceuticals, endocrine disrupting chemicals, algal toxins and microorganisms such as *Cryptosporidium*, *Giardia* and viruses. Extending the control of water quality from the final product at the tap to the whole production process will, when accompanied by adequate information to the public, boost the confidence of European consumers in the safety and wholesomeness of their drinking water. Close cooperation between the European Commission and WHO is a prerequisite for achieving this target.

1.2 DRINKING WATER REGULATIONS IN THE UNITED STATES

1.2.1 Introduction

Public water systems in the United States provide high quality drinking water to millions of Americans each day. The application of the multi-barrier concept – that is, selecting and protecting the best available source, using water treatment to control contaminants, and preventing water quality deterioration in the distribution system – has virtually eliminated waterborne diseases of the past such as typhoid and cholera. Nevertheless, some challenges to the safety of the water supply remain. Waterborne disease outbreaks caused by pathogenic microorganisms and toxic chemicals continue to be reported. Contamination of surface and groundwater supplies with various natural and man-made substances may pose either acute or chronic risks if treatment is inadequate. Post-treatment contamination of the distribution system may also pose public health risks. Special groups, such as infants or those with weakened immune systems, may be particularly sensitive to the effects of certain waterborne pathogens and chemicals.

In response to these concerns, the US has enacted strong legislation to ensure the safety of the nation's drinking water supply. The Safe Drinking Water Act (SDWA) authorizes the US Environmental Protection Agency (EPA) to establish national health-based standards that reduce public exposure to microbiological, chemical and radiological contaminants of concern. These federal standards currently apply to approximately 170 000 public water systems throughout the US.[1]

1.2.2 History of the Safe Drinking Water Act

The first national standards for drinking water quality were established by the US Public Health Service in 1914. These standards addressed the bacteriological quality of drinking water and applied only to interstate carriers such as ships and trains. The Public Health Service revised and expanded these standards in 1925, 1946 and 1962, with the latter including regulations for 28 substances. Throughout the 1960s and early 1970s, both the public and Congress became increasingly concerned about the contamination of water supplies by agricultural and industrial chemicals. Surveys indicated that many treatment facilities across the country had major deficiencies. The heightened public awareness about this and other environmental problems led the US government to pass a number of important environmental and public health laws. One of these laws, the Safe Drinking Water Act (SDWA), was passed in 1974 and subsequently amended in 1986 and 1996.

[1] Public water systems regulated by EPA may be publicly- or privately-owned, and must serve at least 25 people or 15 service connections for at least 60 days per year. Bottled water is regulated by the US Food and Drug Administration.

1.2.3 Development of Regulations

Overview

The regulatory development process under SDWA begins with an evaluation by EPA of the available science on the health effects and occurrence of a drinking water contaminant. If a contaminant is considered to pose a potential public health risk, EPA conducts a more extensive analysis that involves a detailed review of health effects, occurrence, treatment options, available analytical methods, costs, and benefits. Outside stakeholders, representing groups such as the water industry, environmental and community associations, State regulators and public health organizations, are involved throughout the regulatory development process. EPA then publishes a proposed regulation and solicits public comments. A final regulation is published after considering public comments and any new information that may become available.

Drinking water standards

Each regulated contaminant has a non-enforceable health goal, or maximum contaminant level goal (MCLG), and an enforceable limit, or maximum contaminant level (MCL). An MCLG is established at the level of a contaminant in drinking water for which there is no known or expected health risk. The MCLG is set at zero for microbial pathogens as well as for chemicals that may cause cancer through a nonthreshold mechanism of action. If there is evidence that a carcinogen may exhibit a threshold below which cancer may not occur, the MCLG is set at a level above zero that is considered to pose no risk. For chemicals that are of concern due to the potential for adverse health effects other than cancer, the MCLG is based on the calculation of a reference dose (RfD). The RfD is an estimate of the amount of a chemical that a person can be exposed to on a daily basis that is not anticipated to cause adverse health effects over a person's lifetime. The reference dose is converted into a drinking water exposure level (DWEL) by incorporating default exposure assumptions for body weight (70 kg) and for average daily consumption of drinking water (2 l per day). The DWEL is then used to calculate an MCLG by adjusting it to account for sources of exposure other than drinking water, such as food and air. An MCLG is designed to be protective of sensitive sub-populations that may be at greater risk than the general population (e.g., infants, the elderly, those with compromised immune systems). In addition, an MCLG may be set at levels that are not measurable or quantifiable by currently available analytical methods.

SWDA requires the EPA to promulgate National Primary Drinking Water Regulations (NPDWRs), which specify enforceable maximum contaminant levels (MCLs) or treatment techniques for drinking water contaminants. An MCL is established at a level that is as close to the MCLG as is technically and economically feasible. A treatment technique may be set instead of an MCL if the available analytical methods

are not adequate. NPDWRs contain specific criteria and procedures, including requirements for water monitoring, analysis and quality control, to ensure that the drinking water system is in compliance with the MCL. EPA has established MCLs or treatment techniques for a wide range of microorganisms, disinfectants, disinfection byproducts, inorganic and organic chemicals, and radionuclides (EPA, 2004a).

EPA also sets National Secondary Drinking Water Regulations for contaminants that affect the aesthetic (e.g., taste, color or odor), cosmetic (e.g., skin or tooth discoloration) or technical (e.g., corrosivity or scaling) qualities of drinking water. These non-enforceable guidelines include secondary MCLs and recommendations for monitoring (EPA, 2004b).

1.2.4 Highlights of the Safe Drinking Water Act

Implementation of the 1986 Amendments to SDWA led to the development of a number of important rules, including the Total Coliform Rule, the Surface Water Treatment Rule, the Lead and Copper Rule, and regulations for a large number of chemicals of public health concern. All public water systems using surface water sources were required to disinfect and provide specific levels of treatment for microbial pathogens; most systems were required to filter their water. In addition, the 'best available technology' was specified for the treatment of contaminants for which an MCL was established.

The 1996 Amendments greatly enhanced the previous regulatory approach in many respects. In addition to reinforcing the use of sound science in fulfilling the requirements of the Act, a cornerstone of the 1996 Amendments is the fundamental requirement for EPA to use a risk-based standard setting process. The amendments place a strong emphasis on protecting source waters, improving the regulatory process, and conducting research on contaminants of concern. Provisions address the special needs of small water systems, and include requirements for making water quality information available to consumers, conducting health risk reduction benefit analyses, and helping states meet water system infrastructure needs. The EPA is required to develop rules to achieve the goal of providing protection from microbial pathogens while simultaneously ensuring decreasing health risks to the population from disinfection byproducts. A brief discussion of some of the major regulatory and nonregulatory provisions of SDWA is found below.

Regulated contaminants

Six-year review of existing regulations The EPA is required by the 1996 SDWA Amendments to review each NPDWR at least once every 6 years. Revisions must maintain or increase public health protection. In consultation with stakeholders, the EPA developed a systematic approach for the review of the NPDWRs. This protocol was applied to the Agency's initial Six-Year Review of most of the NPDWRs

published prior to the 1996 Amendments. In 2003, EPA published final decisions to not revise 68 chemical NPDWRs and to revise the Total Coliform Rule (TCR). The schedule for reviewing NPDWRs established after 1996 will be based on the respective promulgation dates of these rules (EPA, 2004a, c).

The TCR, published by EPA in 1989, requires all public water systems to monitor for the presence of coliforms (measured as 'total coliforms') in their distribution systems. Coliforms serve as indicators of many enteric pathogens, and are therefore useful in determining the vulnerability of a system to fecal contamination. In reviewing microbial risks with a federal advisory committee, EPA determined that the available data on distribution system risks warranted further analysis. Potential revisions being considered may lead to the establishment of requirements to address the quality of finished water in distribution systems (EPA, 2004d).

Microbial/disinfection byproduct rules Minimizing the potential health risks associated with exposure to disinfection byproducts (DBPs) without compromising the safety of drinking water from a microbiological perspective poses a major challenge for drinking water providers. In keeping with a phased Microbial/Disinfection Byproduct strategy agreed to by stakeholders and affirmed by the 1996 SDWA Amendments, the EPA has proposed or finalized a number of rules that address both microbial and DBP concerns (EPA, 2004e). The Stage 1 DBP Rule, finalized in 1998, established Maximum Residual Disinfectant Levels (MRDLs) and Goals (MRDLGs) for three disinfectants; MCLGs and MCLs for trihalomethanes, haloacetic acids, chlorite and bromate; and a treatment technique for removal of DBP precursor material. A new Stage 2 DBP Rule, which will be promulgated in 2005, will provide additional public health protection from the potentially harmful effects of DBPs. The proposed rule retains the Stage 1 MCLs but includes revised requirements for collecting monitoring data and calculating compliance. The rule also requires an initial distribution system evaluation that targets the highest risks by identifying compliance sites with the highest DBP occurrence levels in the distribution system.

A series of microbial rules is being developed and implemented concurrently with the DBP rules. The first of these rules, the Interim Enhanced Surface Water Treatment Rule (IESWTR), was finalized in 1998. Key provisions include treatment requirements for *Cryptosporidium* for filtered water systems, tightened turbidity standards, and inclusion of *Cryptosporidium* in the watershed control requirements for unfiltered public water systems. In 2002, EPA finalized the Long-Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR). This rule extends the provisions of the IESWTR to cover all system sizes, particularly those serving $<10\,000$ individuals. The LT1ESWTR improves control of *Cryptosporidium* in drinking water and addresses risk trade-offs with DBPs. The next generation of surface water treatment rule, the LT2ESWTR, coincides with the proposal and promulgation of the Stage 2 DBP Rule. The LT2ESWTR will strengthen protection against *Cryptosporidium* in the highest risk systems.

The Ground Water Rule (GWR) is a targeted strategy to identify ground water systems at high risk for fecal contamination. The proposed rule establishes a multiple barrier approach to identify and provide corrective measures for public ground water systems at risk of fecal contamination. The GWR will be issued as a final regulation in 2006.

Unregulated contaminants

The 1996 Amendments include a risk-based contaminant selection and decision making process for unregulated contaminants. The EPA must decide whether or not to regulate at least five contaminants every 5 years, based on a consideration of the following three criteria: (i) that the contaminant adversely affects human health; (ii) that it is known or substantially likely to occur in public water systems with a frequency and at levels of public health concern; and (iii) that regulation of the contaminant provides a meaningful opportunity for health risk reduction.

Every 5 years, the EPA is required to develop a list of unregulated microbiological and chemical contaminants that may be regulated by the EPA at some future date (EPA, 2004f). The list, referred to as the Contaminant Candidate List (CCL), was first published by EPA in 1997 and finalized in 1998 after extensive consultation with stakeholders. In establishing the CCL, EPA divided the contaminants into three major categories: (i) a Regulatory Determination Priorities Category, with contaminants that have enough data to determine whether a regulation is necessary; (ii) a Research Priorities Category, which contains contaminants with additional research needs in the areas of health effects, treatment, and/or analytical methods; and (iii) an Occurrence Priorities Category, with contaminants for which additional occurrence data are needed. The 1998 CCL included 50 chemicals and 10 microbial pathogens, most of which were in the Research and Occurrence Priorities Categories.

In 2003, the EPA announced its determination that no regulatory action was appropriate or necessary for nine contaminants on the first CCL. These contaminants included aldrin, dieldrin, hexachlorobutadiene, manganese, metribuzin, naphthalene, sodium, sulfate, and *Acanthamoeba* (for which guidance was developed). A second CCL, issued in 2005 (EPA, 2005), included all the contaminants from the previous CCL for which a regulatory determination was not made. The EPA is developing a more rigorous process for selecting contaminants for future CCLs, using guidance from the National Academy of Sciences (2001) and the National Drinking Water Advisory Council (2004).

National Occurrence Data Base and the Unregulated Contaminant Monitoring Rule

SDWA has provisions that provide for the collection, organization and sharing of occurrence data on contaminants of potential concern. The National Drinking Water

Contaminant Data Base (NCOD) is a website repository of water sample analytical data on both regulated and unregulated contaminants in public water systems (EPA, 2004g). These data are used to support listing and regulatory determinations on contaminants for which regulations do not currently exist, as well as reviews of existing regulations and monitoring requirements. Under the requirements of the Unregulated Contaminant Monitoring Rule (UCMR), EPA is required to issue a list every 5 years of up to 30 unregulated microbiological, chemical and radiological contaminants for which monitoring is required by water utilities across the country (EPA, 2004h). Depending upon the availability of adequate analytical methods and current contaminant occurrence data, UCMR contaminants may be subjected to the full assessment monitoring, a screening survey, or a pre-screen testing. This rule has important implications for the development of new or improved analytical detection methods for contaminants of potential public health concern.

Prevention approaches

The 1996 amendments include an important new emphasis on preventing contamination problems through source water protection and enhanced water system management. Source water protection is an ongoing process that includes conducting assessments to understand the vulnerabilities of the source to contaminants, monitoring to detect contamination as early as possible, protecting sources using best management practices, and planning for quick response when contamination occurs. The central responsibility for source water assessments, as well as designing and implementing prevention programs, resides with the states. The states also have the responsibility for building the capacity of local water systems to improve system operations and avoid contamination problems.

The national Wellhead Protection Program, established under the 1986 amendments, is a pollution prevention and management program used to protect underground sources of drinking water. States may use the funds from the SDWA-authorized Drinking Water State Revolving Fund to support a mixture of source water-related local assistance activities. Source water protection activities are also supported by other statutory authorities, particularly the Clean Water Act (CWA), the Resource Conservation and Recovery Act (RCRA), the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

1.2.5 Implementation of Regulations

Once the EPA publishes a final regulation, systems usually have 3 years before they must be in compliance. The states are typically responsible for the implementation and enforcement of standards established by the federal government. The EPA provides oversight, funding and technical assistance to help states administer their

programs. Compliance with the standards is determined through the collection, testing and reporting of samples taken from water systems at designated intervals and locations. The use of EPA-approved analytical methods and certified laboratories (EPA, 2004i) is required for compliance monitoring.

In cases of non-compliance, different types of violations may occur: (i) MCL violations; (ii) treatment technique violations; or (iii) monitoring and reporting violations. Varying levels of public notification are required depending on the type of violation, and corrective action must be taken to remedy the situation. EPA works with the states to enforce drinking water standards.

1.2.6 Conclusions

The US has achieved considerable success in ensuring the safety of the public drinking water supply, particularly since SDWA was first passed over 30 years ago. This has been accomplished through the combined efforts of drinking water and health professionals at the federal, state and local levels. Source water protection programs have been implemented, disinfection of public water supplies has become widespread, and regulations to reduce public exposure to a wide range of contaminants have been established. Sensitive analytical detection methods have made it possible to detect a wider range of microbes and chemicals at increasingly lower environmental levels, and improved treatment technologies have become available. In addition, the public has become much more informed and involved in decisions about the safety of their water supply. Effective implementation of SDWA requirements and the cooperation of the drinking water community will continue to be necessary in the coming years in order to meet the challenges posed by new concerns about the quality and quantity of the nation's drinking water supply.

1.3 STANDARDIZATION

1.3.1 Introduction

Legislative directives on the quality of drinking water call for wholesome, clean, and safe water. The European directive, as an example, specifies that the analytical methods used for drinking water should ensure that the results obtained are reliable and comparable (Council Directive 98/83/EC, 1998). Possible risks for the consumer of drinking water from various toxic and health concerns shall be investigated and monitored, e.g. chemical or microbiological contaminants from natural sources or pollutants from material being in contact with drinking water. The result of these investigations is a list of contaminants including an upper limiting value for each of the parameters. Drinking water directives, such as that from the European Union (EU) (Council Directive 98/83/EC, 1998), publish such lists.

1.3.2 Requirements to be Met by Laboratories and Analytical Methods

An effective control of drinking water quality generally is based on data obtained from samples analysed in laboratories.

Regulators, clients, and consumers expect to receive a 'true' result from the laboratory. In order to avoid a semantic discussion about 'what is the true result?', legislators generally define quality requirements to be met by the analytical method and by the laboratory. The minimum requirements to be met by the analytical methods used, according to the European directive (Council Directive 98/83/EC, 1998), shall be capable of measuring concentrations equal to the parametric value with a specified trueness, precision, and limit of detection.

Laboratories shall operate a system of analytical quality control that is subject to checking from time to time by a person who is not under the control of the laboratory and who is approved by the competent authority for that purpose (Council Directive 98/83/EC, 1998). A suitable direction for such a competence check is available (EN/ISO/IEC 17025, 2005). Laboratories qualified for drinking water analyses should fulfill the requirements for an accreditation procedure preferably according to EN/ISO/IEC 17025 (2005).

The laboratories need validated methods for performing a variety of required characteristics, e.g. robust against possible matrix interferences or matrix changes (e.g., hardness), specific and selective for the contaminant of interest, suitable working range, applicable for the control of a maximum contaminant level. Additional desirable characteristics are that the methods should, for example, allow simplified sample preparation, rapid analyses, economical benefits, avoidance of hazardous reagents (e.g., certain solvents), robust apparatus, compatible with the requirements of an analytical quality control (AQC) system.

Approved and validated methods appropriate for drinking water analyses are generally standardized methods. These methods have normally been developed especially for drinking water analyses. During the standardization project the draft standard methods have to go through a validation procedure, including checks for trueness, precision, recovery, and finally an interlaboratory trial before they are published as a standard method.

1.3.3 Standardization in CEN TC 230 Water Analysis and ISO TC 147 Water Quality

General

Standardization is one of the tools used to organize the technical world. Standardization has become an integral component of the economic, social, and legal systems.

International standards from the International Standards Organization (ISO) and European standards (EN) from the European Standardisation Organization (CEN) can remove trade barriers and promote business across national frontiers. Standardization is based on consensus, on scientific findings and on technical progress, and one has to bear in mind the economic consequences (DIN, 1998).

Standardization in CEN and ISO has to be well-founded. Before the work on a new standardization project can start the applicant country has to explain the need and reason for a new standard (see Section 1.3.4 stage 2).

The philosophy of setting standards in CEN and ISO on the one hand and the US Environmental Protection Agency (EPA) on the other hand is different. CEN and ISO prefer documents that do not specify trademarks or equipment produced by a single manufacturer (monopolies), whenever possible (ISO/IEC, 2001) (see Section 1.3.6).

Standard methods (e.g., from ISO, CEN, and EPA) can be adopted as recommendations on a voluntary basis by any laboratory around the world. Governments can decide to incorporate existing standards into their national standards. European standard methods are essential for the national standards politics in Europe: generally, CEN standards shall replace any of the national standard methods within the European member bodies in order to harmonize analytical standard methods (ISO/TC 147, 2003).

Standardization on a European level is the responsibility of CEN. Standardization on an international level is the responsibility of ISO. Today, some 120 national standardization bodies cooperate in activities that aim to stimulate cooperation in the scientific, technical, and economic spheres across national frontiers. Generally, European standards (EN) are based on ISO standards (DIN, 1998).

CEN and ISO standards are elaborated in technical committees (TC) installed for a particular field of action. ISO/TC 147 'Water Quality', founded in 1971, is responsible for the standardization of water analysis methods. The corresponding European committee is CEN/TC 230 'Water Analysis', founded in 1990 (ISO/TC 147, 2003).

Vienna Agreement

Today, CEN and ISO cooperate according to the so-called Vienna Agreement of 1991 in order to save resources and to avoid duplication of work or contradictory standard methods in CEN and ISO. Both organizations agreed on basic principles, for example, on synchronized approval procedures or simultaneous publication. Standardization projects started in ISO can be transferred to CEN, if necessary, and vice versa. The transfer process can be started either by the so-called unique acceptance procedure (UAP, see Section 1.3.5) on a finalized ISO or CEN standard or by the parallel voting procedure (PVP, see Section 1.3.5) on a document qualified for an enquiry process (ISO/CEN, 2001).

Today, most of the standards on water quality are elaborated in ISO/TC 147 before they are transferred to CEN (ISO/TC 147, 2003). Section 1.3.4 describes the

procedural steps for the standards elaboration in ISO because they need to meet the requirements for approval in CEN, too.

1.3.4 Development of Standards in ISO/TC 147

General

Today, ISO/TC 147 is subdivided into five subcommittees (SC) working on:

- SC 1 terminology;
- SC 2 physical, chemical, and biochemical methods;
- SC 4 microbiological methods;
- SC 5 biological methods;
- SC 6 sampling.

Each of the subcommittees has set up several working groups (WG). Usually, work items will be allocated to a working group.

National member bodies decide which of the committees they want to support. Member bodies are asked to state their opinion of a distinct field of work by commentaries and by voting on items.

ISO standard methods are developed according to the ISO/IEC Directives, Part 1 (ISO/IEC, 1995). Each of the development stages ends in a decision about whether the project should be continued, postponed, or withdrawn. The ISO Central Secretariat (ISO/CS) in Geneva, Switzerland is responsible for all of the formal aspects (e.g., controlling the standardization process, observance of deadlines for voting processes, distribution of all documents, etc.). The working group is responsible for the technical and editorial work and shall report to the subcommittee (SC) and the technical committee. In ISO/TC 147 Committees and working groups generally meet every 18 months.

Development of standards follows a seven-step procedure (ISO/IEC, 1995). See Table 1.1 for the principles of the ISO standardization process.

Stage 1 – Preliminary

The preliminary stage is applied to a new project. The introduction of a new item requires a simple majority vote of the respective committee member bodies. This stage has no target dates to be considered. The advantage of working without time pressure can be used to prepare a carefully thought out initial draft for the proposal stage.

Table 1.1 Standards development according to ISO/IEC Directives

Stage	Business	Requirements/Comments
1 Preliminary stage	ISO member applies for a new standard proposal	Give purpose and justification for the need of new method
		Approval by a simple majority
2 Proposal stage	Written ballot on a new work item proposal (NP) by members within three months necessary	Approval by a simple majority of member bodies *and* a minimum of five members shall participate actively in the project
3 Preparatory stage	Preparation of a working draft (WD)	Elaboration of a WD for circulation to the members
4 Committee stage	Preparation of a committee draft (CD) and its circulation to all member bodies to comment on it within 3 to 6 months	Consensus, this means a two-thirds majority of member bodies voting on the CD should be in agreement
5 Enquiry stage	Preparation of a Draft International Standard (DIS) and its circulation. Voting period: 5 months. A positive vote may contain minor technical comments	Approval of more than 66.7 % members necessary *and* a maximum of 25 % or fewer disapprovals allowed
6 Approval stage	Preparation of a Final Draft International Standard (FDIS) and its circulation. Voting period: 2 months	Approval of more than 66.7 % members necessary *and* a maximum of 25 % or fewer disapprovals allowed
7 Publication stage	Publication of an ISO standard method	The method is valid for 5 years
Review of a standard	Confirmation of the standard method every 5 years	The method is valid for another 5-year period
Withdrawal of standard	Withdrawal of a standard method, if the standard did not pass Stage 7 successfully or a confirmation at the revision date was not permitted	The method will be deleted from the standards project list

Stage 2 – Proposal

The proposal stage is used for a new standard, and for any amendment and/or revision of an existing standard. A new work item proposal (NP) may be made to the respective committee by, for example, a national body, the secretariat of that technical committee or subcommittee, or an organization in liaison. The applicant has to indicate, among other things, the subject of the proposed item, clarification of the scope and, if necessary, what is excluded, plus specific aims and reasons for a new standard.

Where possible, a draft (e.g., elaborated in the preliminary stage) should be sent out with the new work item proposal, but as a minimum an outline should be attached for the voting procedure. Votes shall be returned within 3 months, and comments on the new proposal are encouraged.

Approval of the new proposal requires a simple majority of the committee members voting on the proposal and at least five member countries willing to participate actively in the project.

Stage 3 – Preparatory

The approved new project will be allocated to a working group. Experts nominated for the participation in the project shall agree on a working group member to act as convenor. The working group prepares a working draft (WD). The working draft should be available within 6 months. The convenor of the working group is responsible for the progress, the editorial work, and the preparation of the working draft according to the target dates.

At the end of this stage the working draft is circulated among the members of the technical committee or subcommittee as a first committee draft (CD).

Stage 4 – Committee

The committee stage is used to circulate the first committee draft to all member bodies for consideration. Votes and comments shall be returned to ISO within 3 months. ISO shall circulate the result of the ballot and a compilation of comments to all member bodies not later than 4 weeks after the closing date for voting. The secretariat shall also indicate its proposal on how to proceed with the project.

Formal approval of the Committee Draft requires a two-thirds majority of the member bodies voting, but ISO sets a high value on the consensus principle.

Following the consensus principle in ISO, every attempt shall be made to resolve all of the negative votes and comments received. That may require the preparation and circulation of a second or subsequent versions of the committee draft until consensus has been reached or a decision to postpone or withdraw the project has been made. When the approval requirements have been met, an enquiry draft can be circulated. Ideally, the period between Stage 4 and Stage 5 should be used to organize and evaluate an interlaboratory trial (see Section 1.3.6). The performance characteristics obtained should be sent out with the proposal for the enquiry draft.

Stage 5 – Enquiry

At the enquiry stage the Draft International Standard (DIS, enquiry draft) shall be available in English and French for circulation to the national member bodies. Votes

and comments shall be returned to ISO within 5 months. ISO shall circulate the following documentation:

- result of the ballot;
- compilation of comments received;
- action taken on the comments,

to the national bodies not later than 3 months after the closing date for voting. The secretariat shall also indicate its proposal for proceeding with the project.

Approval of the enquiry draft requires a two-thirds majority of the member bodies voting in favour and a total number of negative votes of not more than 25 % (*Note*: negative votes without a statement about substantial reasons for the disagreement and abstentions are excluded from the total number of votes).

Comments received after the set voting deadline should be considered at the revision phase of the standard method.

The consensus principles remain valid at the enquiry stage, too. When the approval requirements have not met the enquiry draft, comments shall be discussed at a meeting of the committees (TC 147, SC 2) or of the working group, or a revised enquiry draft for voting on it, or a revised committee draft for comments shall be prepared and circulated.

When the approval requirements have been met, the enquiry draft can be forwarded for the preparation as a Final Draft International Standard (FDIS).

Stage 6 – Approval

At the approval stage the Final Draft International Standard (FDIS) shall be distributed within 3 months to all national bodies for a vote within 2 months. All negative votes shall state the technical reasons for disagreement.

Approval requirements for the FDIS are identical to those at the enquiry stage (see above).

If the FDIS fails the approval requirements, the draft shall be referred back to the technical committee or subcommittee and comments shall be discussed at the next meeting. Alternatively a revised enquiry draft for voting on it or a revised committee draft for comments shall be prepared and circulated.

If the FDIS meets the approval requirements, the FDIS can be forwarded to the publication stage.

Stage 7 – Publication

The publication stage ends with the publication of the international standard.

Five-year revision

Standards are valid for 5 years. After that period a decision shall be made to confirm the standard for a further 5 years, to revise it, or to delete it from the working programme.

Withdrawal of standards

Methods shall be deleted from the standards system if they do not pass the approval stage (see above) successfully, or a confirmation after 5 years is refused, or a replacement of an existing standard by a new one takes place.

1.3.5 Special Standards Development Procedures

Some alternative development procedures, within the requirements defined by ISO or CEN, may be applied. Alternative procedures can be beneficial for a standardization organization deciding to adopt an existing document. These alternative procedures offer the following advantages:

- resources can be saved;
- the duplication of work can be avoided;
- the speed of standards elaboration can be increased;
- consensus need to be established only once (ISO/CEN, 2001).

Fast-track procedure

This procedure may be applied if a standard method, developed by another organization is available and appropriate for a ISO standardization project. A standard method submitted directly for approval as an enquiry draft (DIS, Stage 5, see above) starts on the proposal stage (Stage 2 above). After the approval of the project it can be forwarded directly to the enquiry stage (Stage 5 above) without passing through the preparatory stage and committee stage (above), thus speeding up the development process (ISO/IEC, 1995).

Transfer of standard methods according to the Vienna Agreement

The cooperation between ISO and CEN follows the Vienna Agreement (ISO/CEN, 2001), see Section 1.3.3. Standards can be transferred to the other organization either

by the unique acceptance procedure (UAP, see section below) or by the parallel voting procedure (PVP, see section below).

Unique acceptance procedure (UAP) The organization (CEN or ISO) that wants to adopt an available standard method from the other organization submits it to its own adoption, voting, and publication procedures. The approved standard to be transferred will be balloted at the enquiry stage of the adopting organization (ISO/DIS or CEN enquiry, respectively). After the positive vote the adopted document can be finalized and published.

The technical content of the publication of the adopted standard should be identical with that of the original publication. Any intended technical alterations or changes shall be discussed and resolved with the secretariat of the developing organization in order to find a satisfactory solution. Ideally, the original standard should be revised according to the PVP (below) if a consensus about the intended changes cannot be reached and the adopting organization decides to insist on the changes. If this is not possible, the amended standard shall include information and reasons for the alteration of the original document (ISO, 2004).

Parallel voting procedure (PVP) This procedure is suitable for transferring projects already started. Once the decision has been made about a CEN or ISO project leadership, the responsible committee drafts a document according to the procedures of the leading organization. The responsible secretariats of CEN and ISO shall ensure the synchronization of the ISO/DIS–CEN enquiry for parallel voting. After a positive vote in CEN and ISO, the adopted document can be finalized and published. Otherwise consultations between CEN and ISO are necessary in order either to resolve the negative votes responsible for the disagreement or to proceed in accordance with the own rules of the respective organization (ISO, 2004).

1.3.6 Drafting of Standards

Besides formal aspects of standardization, analytical standard methods have to follow a general structure with several obligatory technical instructions in the normative body of the standard. The ISO Directives, Part 2 (ISO/IEC, 2001) give advice for the structure of ISO standards. Standard developers can gain supplementary information from a model manuscript (ISO, 1998a). See Table 1.2 for an example of the structure of a EN ISO standard method.

This concept ensures a strict definition of the application range of the standard to be applied. In addition, informative annexes may be presented in order to give further examples and information to the user. The normative part of an analytical standard method in CEN and ISO includes at least the clauses listed below (ISO/IEC, 2001; ISO, 1998). Additional clauses, such as specific definitions or a list of minimum requirements needed, may be added to the standard, if relevant.

Table 1.2 Structure of EN/ISO 15061 (2001). EN/ISO 15061 Water quality – Determination of dissolved bromate: Method by liquid chromatography of ions

Foreword
Introduction
1 Scope
2 Normative references
3 Interferences
4 Principle
5 Essential minimum requirements
6 Reagents
7 Apparatus
8 Quality requirements for the separator column
9 Sampling and sample pretreatment
10 Procedure
11 Calculation
12 Expression of results
13 Test report
Annex A (informative) Eluents
Annex B (informative) Regeneration solutions
Annex C (informative) Example of column switching technique
Annex D (informative) Interlaboratory trial
Annex E (informative) Checked interferences
Bibliography

Title

The title shall be concise and represent the parameter (sometimes also the analytical technique and matrix, if relevant) treated in the standard (ISO, 1998a). The user of the standard shall be aware that the method is strictly limited to the mentioned sample matrices and any analytical result based on an extension or alteration of the standard method in the user's laboratory cannot refer to the standard method.

Foreword

A foreword shall appear in each standard. It gives the designation and name of the technical committee and subcommittee that prepared the standard (ISO, 1998a).

Introduction

The introduction is an optional element containing commentary about the technical content of the standard or background information (ISO/IEC, 2001).

Scope

The scope specifies briefly the applicability (e.g., parameter to be determined, working range to be applied, appropriate sample matrix types) and the limitation of the method (ISO, 1998a). Limitation means exclusion of any expansion or changes of the standard method (e.g., addition of parameters or sample matrix types not listed).

Normative references

This clause lists a number of other standard methods essential for the application of the standard. Draft International Standards may also be cited in the list. All other documents, for instance any used for the development of the standard, may be listed in an informative bibliography (ISO, 1998a).

Interferences

This section gives information on the technical limitations of the standard method caused by, for example, sample matrix effects (coloured samples can interfere with the photometric detection or element specific spectral interferences (AAS, ICP-OES) or chemical interferences (precipitation reactions, formation of reaction by-products). These details are validated experimentally in laboratories participating actively in the standardization work. The documentation of the interferences may help potential users of a specific standard to decide whether the standard method could be applicable for the requirements of their analytical businesses.

Principle

This clause gives a brief overview of the procedural basis of the analytical method.

Reagents

This clause contains a list of reagents and/or solutions used in the method (ISO/IEC, 2001) including information on the required purity grade as well as concentrations of solutions.

Apparatus

This section defines the analytical system to be used for the determination of the parameters listed in the title of the standard (ISO/IEC, 2001). The suitability of the specified apparatus has also been checked experimentally. Standards developers

generally check different technical systems and appropriate alternative equipment, if this exists. Finally, the standards developers (working group members) decide which one of the possible alternative systems shall be part of the normative body of the standard. If applicable, alternative systems can be presented in an informative annex.

CEN and ISO standard developers should not refer to a sole supplier (monopoly situation). Equipment offered by a single manufacturer should not be specified. Where such equipment is not commercially available, detailed specifications for the equipment shall be given in order to enable all users to test comparable apparatus and systems (ISO/IEC, 2001).

Sampling and sample pre-treatment

Generally, this clause refers to an international standard, if such exists. If necessary, specific preconditions and methods of sampling or pre-treatment steps for the preservation of the samples (e.g., filtration, acidification, bottle material, storage conditions) are given.

Procedure

This clause gives advice about all of the procedural elements used for determination of the parameters. This includes the preparation of the test sample, the set-up procedure of the analytical system, the calibration strategy, and the measurement of the sample.

Calculation

This element gives instructions on how to convert a measured value obtained from the parameter of interest into a mass concentration, including the method of calculation (e.g., use of the inverse calibration function, consideration of blank values).

Expression of results

This clause defines the report format of the calculated results (e.g., dimension, number of significant figures).

Test report

The test report contains a minimum of information on the sample (e.g., result, identification data of the sample, applied standard method).

Interlaboratory trial

The presentation of statistical results of data from interlaboratory trials can be handled differently in CEN and ISO. CEN presents these data generally in the normative body of the standard, whereas ISO puts them in the informative annex of the standard. Besides the different philosophies in ISO and CEN on the layout of a standard, the organization and evaluation of an interlaboratory trial is obligatory for the standard developers in CEN and ISO, and the quality of the statistical data from the interlaboratory trial is the final categorical factor in the decision to publish the standard method, to postpone or to withdraw the project from the working list. The criteria for interlaboratory trial data to be met are given in ISO 5725, Part 2 (ISO, 2002).

1.3.7 EU Requirements for Standard Methods

General

Analytical methods used for the control procedures according to the European drinking water directive must be capable of measuring concentrations equal to the parametric value (Council Directive 98/83/EC, 1998). This is a positive requirement and enables laboratories to choose a suitable method among alternatives. The European directive additionally specifies quality requirements concerning trueness, precision, and the limit of detection of the method (see Table 1.3).

The performance characteristics of a method, obtained from an interlaboratory trial (see above), give a first indication of the suitability of an analytical method.

Table 1.3 Parameters with specified performance characteristics

	Trueness	Precision	Limit of detection
Parameters	% of parametric value		
Anions and Oxidizability			
Cl^-, CN^-, Cr(VI), F^-, $NO_3{}^-$, $NO_2{}^-$, $SO_4{}^{2-}$	10	10	10
$BrO_3{}^-$	25	25	25
TOC	25	25	10
Elements and Ammonium			
Al, As, B, Cd, Cu, Fe, Mn, Na, Ni, Pb, Se, NH_4^+	10	10	10
Hg	20	10	20
Sb	25	25	25
Organic parameters			
1,2-Dichloroethane, tetrachloroethene, trichloroethene, trihalomethanes (total)	25	25	10
Benzo(*a*)pyrene, benzene, pesticides, PAHs	25	25	25

However, it is the duty of the laboratory to validate each of the methods applied for drinking water analyses and to demonstrate the capability of the laboratory to fulfill the required characteristics according to the EU directive (Council Directive 98/83/EC, 1998).

Estimation of trueness and precision The EU directive (Council Directive 98/83/EC, 1998) refers to the definitions for the determination of trueness and precision given in ISO 5725-1 (ISO, 2002). According to this standard, the estimation of the trueness requires 'a large series' of replicate determinations of test samples. But what does 'large series' mean? Neither ISO 5725-1 nor the EU directive resolve this question. The determination of precision also requires a number of replicate determinations of a test sample. Information on a recommended number of replicates is also missing in ISO 5725-1.

A practicable concept is ENV-ISO 13530 (ENV/ISO/TR, 1998). ENV-ISO 13530 is a guide to analytical quality control (AQC). It is applicable to the chemical and physicochemical analysis of waters including drinking water. It describes an AQC concept applicable to analyses carried out frequently or infrequently as well as for complex, time-consuming, procedures producing only few results at a time (e.g., for the determination of complex organic contaminants).

For the estimation of trueness, ENV-ISO 13530 recommends regular participation in external quality procedures such as interlaboratory trials and proficiency schemes for the control of trueness (bias). For internal routine action, the use of control charts, based on the mean, spiking recovery, and analysis of blanks, is recommended. In addition, the standard recommends the use of a mean and/or a range control chart and the execution of a minimum of six replicate determinations of the test sample for the calculation of the standard deviation for the control of the precision.

Limit of detection The EU directive 98/93/EC (see Table 1.3) sets a requirement to be met for the limit of detection (LOD). The determination of the LOD does not follow a standard method. LOD shall be calculated from replicate determinations, either

(a) multiply the within-batch standard deviation of the reproducibility of a natural sample containing a low concentration of the parameter three times, or

(b) multiply the within-batch standard deviation of the reproducibility of a blank solution five times.

Information on a recommended number of replicates is missing in the directive (Council Directive 98/83/EC, 1998).

The LOD represents a qualitative performance data of the method, only. In contrast to the LOD, the Limit of Quantification (LOQ) would represent data valid for carrying out quantitative determinations. For this reason a revised directive (Council Directive 98/83/EC, 1998) should refer to the LOQ. It is intended to define a calculation procedure for LOQ with the publication of the revised ISO 13530 (ENV/ISO/TR, 2004).

As long as the lowest limit of application of the method is significantly lower than the required LOD, additional experiments for the estimation of the LOD do not need to be carried out. This attribute will be the case for the determination of many anions and cations (see later, Tables 1.5 and 1.6).

Examples for the estimation of laboratory internal performance data ENV-ISO 13530 (ISO/TR, 2003) can be applied to ascertain the laboratory internal values for precision, trueness and LOD according to the EU directive 98/83/EC. The examples in Table 1.4 may give an indication for the internal actions to be applied by the laboratory.

Table 1.4 Example for the estimation of performance characteristics for bromate

Demand for:	Recommended action:
Parametric value 10 μg/l	Execution of a practicable calibration according to ISO 8466-1 (1990) or ISO 8466-2 (2001), e.g. working range 2.5 μg/l to 25 μg/l BrO_3^-
Precision 2.5 μg/l	For frequent determinations: Use the standard deviation of a mean control chart (use of a 10 μg/l BrO_3^- control solution) For infrequent determinations: Calculate the standard deviation from the results of >6 replicate determinations of a 10 μg/l BrO_3^- standard solution *Note*: Whenever available, certified reference materials should be used.
Trueness 2.5 μg/l	*General*: participation in interlaboratory trials, regularly For frequent determinations: Operation of a mean control chart, concentration of the control solution e.g. 10 μg/l BrO_3^- Operation of a recovery control chart, when systematic errors from matrix interferences are expected Measurement of two blank solutions at the beginning and at the end of a batch in order to identify contamination of reagents, of the measurement system and instrumental faults and documentation of the blank values on a blank control chart For infrequent determinations: Measurement of trueness control samples in the lower and upper part of the calibrated working range Replicate measurements of samples Measurement of blanks Measurement of reference material, if available Validity check of the calibration function using material from an independent source
LOD 2.5 μg/l	Inclusion of the LOD value in the calibrated working range (e.g. 2.5 μg/l to 25 μg/l BrO_3^-)

It can be expected that the repertoire of actions recommended in Table 1.4 will be appropriate for the determination of inorganic parameters. For multistage or lengthy procedures that produce only few results at a time, the procedures for infrequent determinations could be carried out. However, this is still problematic for the determination of the performance characteristics for several (ecological important) pesticides where suitable reference materials of appropriate concentration are not available or the LOD requirement are unlikely to be achieved (Council Directive 98/83/EC, 1998).

CEN and ISO standard methods for drinking water analyses

CEN and ISO have already published a number of standard methods suitable for the determination of most of contaminants for the control of the quality of water. For the determination of anions and elements several alternative single and multiple component methods have been approved. For the determination of organic parameters generally multiple-component procedures are available.

Single-component methods are valid for that parameter cited in the scope of the standard, only. Generally, a single-component method requires parameter specific descriptions like sampling procedure, sample preservation and preparation, chemical reaction procedures, and measurement steps. Examples for typical single-component procedures are photometric, electrometric, or atomic absorption spectrometric (AAS) methods. The capital cost for the apparatus is relatively low. However, the obligatory procedural steps may be time consuming and labour intensive.

Multiple component methods are procedures for the determination of more than one parameter at a time. In contrast to single component methods multiple component methods describe a general procedure on sampling, preservation, preparation, and determination for all of the parameters in the scope of the method. Examples for typical multiple component procedures are inductively coupled plasma (ICP-OES or ICP-MS) for element analyses and chromatographic techniques (IC, GC, HPLC). The cost of the apparatus can be very high. However, multiple-component procedures for the determination of inorganic parameters are time saving and labour saving, and offer very high sample throughputs for the laboratories. They are considered to be very cost effective. Multistage procedures like trace level analyses of organic parameters can be time consuming, producing only a few results at a time.

Tables 1.5 to 1.7 present a selection of chemical and indicator parameters with specified requirements according to the EU drinking water directive (Council Directive 98/83/EC, 1998). In Tables 1.5 to 1.7 are listed the parameter, the parameter specific defined maximum contaminant levels, and limits of detection (LOD).

Also listed are recommendations for the application of existing CEN and ISO methods, generally automated multiple-component procedures, suitable for routine analyses with high sample throughput, except for standard methods for the determination of organic parameters which could be time consuming. Nevertheless, any laboratory can choose any alternative method of its choice as long as it is capable of

Table 1.5 Anions and Oxidisability (TOC)

Parameter	Method	Principle[a]	Working range[a] (mg/l)	Parametric value[a] (mg/l)	LOD[a] (mg/l)
Bromate	EN ISO 15061 (2001)	IC	≥0.0005	0.01	0.0025
Chloride	EN ISO 10304-1 (1995)	IC	≥0.1	250	25
Chromium(VI)	ISO/DIS 23913 (2004a)	CFA	≥0.002	0.05	0.005
Cyanide, total	EN/ISO 14403 (2002)	CFA	≥0.01	0.05	0.005
Fluoride	EN ISO 10304-1 (1995)	IC	≥0.1	1.5	0.15
Nitrate	EN ISO 10304-1 (1995)	IC	≥0.1	50	5
Nitrite	EN ISO 10304-1 (1995)	IC	≥0.05	0.5	0.05
Sulfate	EN ISO 10304-1 (1995)	IC	≥0.1	250	25
Total organic carbon (TOC)	EN 1484 (1997a)	Thermic catalytic oxidation	≥1	5	0.5

[a] where:
Parametric value is the required limit according to Council Directive 98/83/EC, 1998.
CFA is continuous flow analyses.
IC is ion chromatography.
LOD is the limit of detection, to be achieved according to Council Directive 98/83/EC, 1998.
Working range is the lowest determinable concentration stated in the method.

Table 1.6 Elements and ammonium

Parameter	Method	Principle[a]	Working range[a] (μg/l)	Parametric value[a] (μg/l)	LOD[a] (μg/l)
Aluminium	EN/ISO 17294-2 (2004)	ICP-MS	≥5	200	20
Ammonium	EN/ISO 14911 (1998)	IC	≥100	500	50
Antimony	EN/ISO 17294-2 (2004)	ICP-MS	≥0.2	5	1.25
Arsenic	EN/ISO 17294-2 (2004)	ICP-MS	≥1	10	1
Boron	EN/ISO 17294-2 (2004)	ICP-MS	≥10	1000	100
Cadmium	EN/ISO 17294-2 (2004)	ICP-MS	≥0.5	5	0.5
Copper	EN/ISO 17294-2 (2004)	ICP-MS	≥2	2000	200
Iron	EN/ISO 11885 (1997b)	ICP-OES	≥20	200	20
Lead	EN/ISO 17294-2 (2004)	ICP-MS	≥0.2	10	1
Mercury	EN 1483 (1997c)	AAS	≥0.1	1	0.1
Nickel	EN/ISO 17294-2 (2004)	ICP-MS	≥1	20	2
Selenium	ISO 9965 (1993)	AAS	≥1	10	1
Sodium	EN/ISO 17294-2 (2004)	ICP-MS	≥10	200 000	20 000

[a] Where:
AAS is atomic absorption spectrometry.
IC is ion chromatography.
ICP is inductively coupled plasma.
LOD is the limit of detection, to be achieved according to Council Directive 98/83/EC, 1998.
MS is mass spectrometry.
OES is optical emission spectrometry.
Parametric value is the required limit according to Council Directive 98/83/EC, 1998.
Working range is the lowest determinable concentration stated in the method.

Table 1.7 Organic parameters

Parameter	Method	Principle[a]	Working range[a]	Parametric value[a]	LOD[a]
Acrylamide	No standard method available in CEN/ISO	To be controlled by product specification		0.1	
Benzene	ISO 11423 (1997a,b)	GC-FID	≥1	1	0.25
Benzo(*a*)pyrene	EN/ISO 17993 (2003b)	HPLC-FD	≥0.005	0.01	0.0025
1,2-Dichloroethane	EN/ISO 10301 (1997d)	GC-ECD	≥5	3	0.3
Epichlorohydrin	EN 14207 (2003a)	GC-MS	≥0.1	0.1	
		To be controlled by product specification			
Pesticides[b]	ISO/EN 11369 (1997e)	HPLC-UV	≥0.1	0.1	0.025[c]
	EN/ISO 15913 (2003c)	GC-MS	≥0.05		
	EN/ISO 6468 (1996)	GC-ECD	≥0.01		
Polycyclic aromatic hydrocarbons	EN/ISO 17993 (2003b)	HPLC-FD	≥0.005	0.1	0.025
Tetrachloroethene	EN/ISO 10301 (1997d)	GC-ECD	≥0.1	10	0.1
Trichloroethene	EN/ISO 10301 (1997d)	GC-ECD	≥0.1	10	0.1
Trihalomethanes, total	EN/ISO 10301 (1997d)	GC-ECD		100	10
Vinyl chloride	No standard method available in CEN/ISO	To be controlled by product specification		0.5	

[a] Where:
ECD is electron capture detection.
FD is fluorescence detection.
FID is flame ionization detection.
GC is gas chromatography.
HPLC is high performance liquid chromatography.
LOD is the limit of detection, to be achieved according to Council Directive 98/83/EC, 1998.
MS is mass spectrometry.
Parametric value is the required limit according to Council Directive 98/83/EC, 1998.
UV is ultra violet detection.
Working range is the lowest determinable concentration stated in the method.
[b] Several organic insecticides, herbicides, fungicides, nematocides, acaricides, algicides, rodenticides, slimicides, their relevant metabolites, degradation and reaction products. Only those pesticides which are likely to be present in a given supply need be monitored (Council Directive 98/83/EC, 1998).
[c] The LOD applies to each individual pesticide and may not be achievable for all pesticides at present (Council Directive 98/83/EC, 1998).

meeting the method performance requirements of the EU directive (Council Directive 98/83/EC, 1998). The third column gives information about the analytical principle and the fourth column indicates the lowest concentration determinable cited in the standard method.

Methods for anion analysis For the determination of anions (except chromate and cyanide), ion chromatographic methods can be applied, because they were developed especially for drinking water analysis. The cited standards and drafts (see Table 1.3)

can be used for the control of the parametric value. For chromium determinations now the new ISO 18412 (ISO, 2005) is suitable for the control of the parametric chromium value of 50 μg/l (see Table 1.5), and the required LOD of 5 μg/l could be achieved by the method. The alternative sensitive CFA draft standard method ISO/DIS 23913 (ISO/DIS, 2004) is expected to be published soon. Both methods are applicable for the determination of chromate concentrations ≥2 μg/l and meet the requirements of the EU directive (Council Directive 98/83/EC, 1998). Reference to the CFA method is given due to the economic advantages of the CFA method (high sample through put).

Methods for elemental analyses For the determination of elements (e.g., lead, cadmium, etc.) the method of ICP-MS (EN Standard, 2004) should be preferred over AAS methods, whenever possible. The ICP-MS determination of iron could be subject to polyatomic interferences so the ICP-OES EN Standard, 1997b method should be applied. For mercury and selenium AAS hydride techniques (EN Standard, 1997c; ISO, 2003b) should be applied due to the higher sensitivity of these techniques compared with the ICP-MS technique (EN Standard, 2004). All of the cited standards (see Table 1.5) can be used for the control of the parametric value.

Methods for organic compounds analyses The very low parametric values for the organic compounds specified in the European directive 98/83/EC require methods suitable for trace level analyses. There is still demand for the development of new standard methods, because no CEN or ISO standard is currently available for the determination of acrylamide, several pesticides, and vinyl chloride.

HPLC-MS and GC-MS techniques have advantages for the determination of organic contaminants due to their high selectivity and sensitivity. For the determination of pesticides, the user has to apply several standards applicable for selected pesticides.

For the determination of highly volatile halogenated hydrocarbons, the GC-MS technique has not been included explicitly in the principles of EN ISO 10301 (EN/ISO, 1997d), so reference is made to the ECD-technique.

The laboratory shall ensure that it can meet the specified parametric values. This could, however, be a problem for the determination of, for instance, 1,2-dichloroethane and benzo(*a*)pyrene.

Alternative test methods Due to the relative high parametric values for chloride, iron, nitrate, nitrite, and sulfate, for example (see Tables 1.5 and 1.6), laboratories should consider the application of alternative methods for the measurements. Compared with reference and laboratory standard methods, the so-called 'ready-to-use methods', such as cuvette tests, allow fast and often inexpensive results, as well as needing reduced quantities of reagents and less waste. Provided they give reliable results, these alternative methods could be considered for use in drinking water analysis. ISO 17381 (ISO, 2003c) lists criteria and requirements for the producers and for the users of these tests.

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